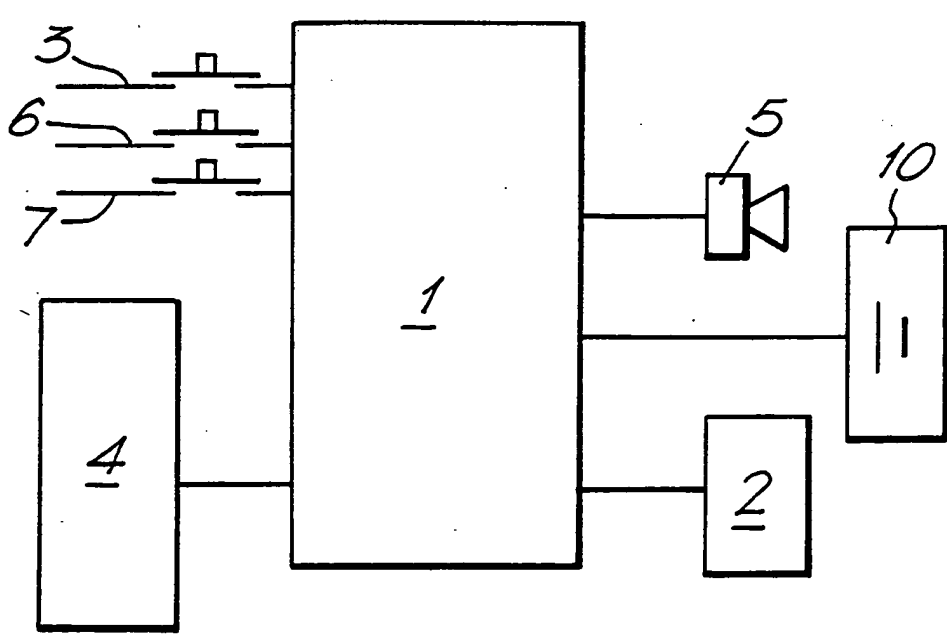




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| (21) International Application Number: PCT/GB87/00804 (22) International Filing Date: 11 November 1987 (11.11.87) (71)(72) Applicants and Inventors: RUSTON, Joseph, Henry [GB/GB]; BARBUR, John, Lazar [GB/GB]; 24 Elvas-ton Place, London SW7 5NL (GB). (74) Agent: SHAW, Laurence; George House, George Road, Edgbaston, Birmingham B15 1PG (GB). (81) Designated States: AT (European patent), AU, BE (Eu-ropean patent), CH (European patent), DE (European patent), DK, FI, FR (European patent), GB (Euro-pean patent), IT (European patent), JP, KR, LU (Eu-ropean patent), NL (European patent), NO, SE (Euro-pean patent), SU, US. | | Published <i>With international search report.</i> |
| (54) Title: PREGNANCY MONITORING DEVICE  <pre> graph LR 3[3] --- 4[4] 3 --- 1[1] 1 --- 5[5] 1 --- 10[10] 1 --- 2[2] </pre> | | |
| (57) Abstract A pregnancy monitoring device to be worn on the body, e.g. as a pendant or bracelet, and including a switch (3) ar-ranged to input fetal movements in a given time period to a microprocessor (1) for display (4). | | |

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Pregnancy Monitoring Device

This invention relates to a pregnancy monitoring device.

Research has shown that movement in the womb is a reliable indication of the health of an unborn child, such movement being known as fetal movement.

Such movements are readily detectable and recordable using the facilities available in hospitals, but while pregnant women are not in a hospital it is advantageous for them to count the number of fetal movements experienced over a specified period each day and report the results when they next visit an ante-natal clinic or their doctor.

Manual methods of recording fetal movement exist whereby a pregnant woman must remember to count the number of fetal movements felt after a pre-arranged start time. When she has counted to ten she looks at her watch and writes down the time. However, the reliability and accuracy of such methods is limited. If there is an abnormality in the pattern of fetal movements, then this may not be noticed. There is no provision for recording each movement as soon as it occurs.

According to this invention a pregnancy monitoring device adapted to be carried by a pregnant woman, comprises a housing containing a microprocessor and having a display capable of selectively displaying the time, the expected delivery date, the time elapsed since the start of pregnancy, and the time remaining until the expected delivery date, the information to be displayed being derived from the microprocessor after the input of the necessary information.

Also according to this invention there is provided a pregnancy monitoring device adapted to be carried by a pregnant woman, comprising input means operative to indicate a fetal movement; a counter arranged to count the number of operations of the input means; and alarm means operative to give an alarm indication to the user when an abnormal pattern of operation of the input means occurs.

An abnormal pattern of operation of the input means can be when no count is started within a predetermined period from commencement of use of the device; when the number of actuations of the input means in a monitoring period is less than a predetermined number; or when an analysis of the number of operations of the input means in each of a plurality, for example three, of monitoring periods indicates an abnormal pattern.

An advantage of the device compared with a manual system is the improved accuracy, but in addition because the fetal movements can be recorded as soon as they occur.

For example, a baby in distress often exhibits an increased kick-rate prior to the kick-rate's decline. With a manual system, there is no provision for recording the rate of kicks. Using a device according to the invention there is an increased detection of an abnormality.

This invention will now be described by way of example with reference to the drawing in which

Figure 1 is a block schematic circuit diagram of a device according to the invention; and

Figure 2 is a diagrammatic front view of the device of Figure 1.

Figure 3a is a table of the modes and registers used in the microprocessor, and to what they relate.

Figure 3b is a flow diagram showing the operation of the circuit.

The device can be in the form of a pendant to hang around the neck or bracelet or wristwatch to be worn around the wrist by a pregnant woman, the device being usable to monitor the pregnancy.

The device comprises a housing 20 containing electronic circuitry and a battery power supply 10 for the circuitry. The circuitry includes a microprocessor 1 and associated real time clock 2 responsive to input signals from an input means in the form of a switch C actuatable by a user of the device, to control a liquid crystal display means 4 and an alarm means 5.

The microprocessor 1 is of known type and comprises an Hitachi model HD63705. The real time clock 2 is of a model type 58321. The display 4 comprises a dot matrix display Hitachi model LM052L. All the components are of known type, but have not previously been arranged to produce a device according to the invention.

The microprocessor provides a first, real time clock operative to indicate normal time; a second clock indicating elapsed pregnancy time, ie how long the user of the device has been pregnant; a third clock indicating remaining pregnancy time, ie time remaining to expected date of delivery; and a fourth clock associated with the counting of

fetal movements and operative to indicate the time taken for ten operations of the input switch 3 indicating fetal movements and also to indicate to the user of the device when each monitoring period should start. Associated with the fourth clock is a counter responsive to the input switch 3 to count the number of operations thereof.

Use of the device is initiated by insertion of the battery 10 whereupon the user sets the clocks in the microprocessor 1, in known manner, such that the first clock can indicate the correct time, the third clock is counting down to the expected date of delivery, and the fourth clock is counting down to the time when the first fetal movement monitoring period is to start. The output of the second clock is calculated in the microprocessor 1 from the readings of the other clocks. The device is then in a wait mode in which the times indicated by the clocks can be displayed on the display means 4 by appropriate operation of the switch 3 on the housing 20.

When the time to start the first fetal movement monitoring period is reached by the fourth clock an audible signal is issued and the display means 4 operated to indicate to the user that a switch 7 should be operated to start a monitoring period. If the switch 7 is not operated the audible signal stops after one minute but is thereafter

repeated at three hourly intervals. On the third repetition with no operation of the switch 7 the device reverts to an alarm mode and the alarm means 5 is operated to give an audible alarm signal.

After operation of the switch 7 the device enters a count mode in which the display means 4 displays the number of operations of the input switch 3 counted by the counter and the elapsed time since the start of the monitoring period. The monitoring period is ended when the counter reaches a count of ten or the elapsed time reaches twelve hours.

The information displayed on the display means 4 at the end of the monitoring period is then stored by the microprocessor. The information may be, for example, the number of fetal movements recorded in each monitoring period of say twelve hours or the times taken to record successive counts of ten fetal movements. The information is displayable on demand for a given period of time, for example, seven days. At the end of this period the information could either be recorded manually, or the device read when the user visits the ante-natal clinic or their doctor.

After the monitoring period the user operates the switch 7 to return the device to the wait mode ready for issue of the

audible signal when the next monitoring period is to be started as determined by the fourth clock.

If the device determines an abnormal pattern of operation of the input switch 3 then the device enters an alarm mode in which the alarm means 5 is operated to give an audible alarm and an alarm display is given on the display means 4. An abnormal pattern of operation of the input switch 3 can be when there is no operation thereof within a predetermined time from commencement of use of the device; when the number of operations of the input switch 3 in a monitoring period is less than a predetermined number; or when an analysis of the number of operations of the input switch 3 in each of a plurality of consecutive monitoring periods indicates an abnormal pattern, the analysis being carried out by the microprocessor 1.

The alarm mode can be cancelled by operation of the switch 3 to return the device to the wait mode ready for another monitoring period to be initiated.

Figures 3a and 3b show, schematically, the nature of the program used by the microprocessor 1.

Referring to Figure 3a this shows the nature of the various modes of operation of the device, and what each mode relates

to. The register shows the variables used within the program, and to what they relate.

Figure 3b shows, schematically, the program used by the device. As shown the program progresses through, checking the state of the flags corresponding to the various modes. If the flag is set, then the program jumps to the subroutine corresponding to that mode.

The interrupt that the microprocessor receives may arise from the kick interrupt routine which is initiated when the 'read' switch 7 is depressed. This routine causes the device to enter the counting mode 1. The timer interrupt routine is initiated from the 1 Hz pulses given out from the real time clock 2. This causes the clocks to increment and decrement the hours and minutes etc. In addition, when the time arrives for the monitoring period to begin, an interrupt is sent and the device is set to mode 1.

The housing of the device has an area (not shown) on which details of the user can be entered in legible form to assist in times of any emergency.

The device described above is intended to be worn by the user throughout pregnancy even though it will not be used to count and monitor fetal movements until say the last twenty

weeks of the pregnancy. During the early weeks the device will serve as a time monitor capable of displaying the times indicated by the first, second and third clocks on the display means 4 by appropriate operation of the switch 30, and will also serve simply as a data carrier to assist in case of an emergency. After experiencing the first fetal movement the user triggers the device by operation of a recessed switch 40, this bringing into operation the fetal movement monitoring functions of the device.

The pregnancy monitoring device is not limited to the embodiment shown. The microprocessor 1 can be such that more sophisticated analysis can be made upon the data. For example, the rate of fetal movements during a monitoring period could be measured and the alarm sounded if there were any abnormal pattern present in this rate.

CLAIMS

1. A pregnancy monitoring device characterised by housing containing a microprocessor (1) and having a display (4) capable of selectively displaying the time, the expected delivery date, the time elapsed since the start of pregnancy, and the time remaining until the expected delivery date, the information to be displayed being derived from the microprocessor after the input of the necessary information by the user.
2. A device according to Claim 1, characterised by input means (3) operative to indicate a fetal movement; a counter arranged to count the number of operations of the input means; and alarm means (5) operative to give an alarm indication to the user when an abnormal pattern of operation of the input means occurs.
3. A device according to Claim 2, characterised in that the alarm means (5) is arranged to give an alarm indication when no count is started within a predetermined period from commencement of use of the device; or when the number of actuations of the input means in a monitoring period is less than a predetermined number; or when an analysis of the

number of operations of the input means in each of a plurality of monitoring periods indicates an abnormal pattern; or when an analysis of the rate of fetal movements within a monitoring period gives an indication of an abnormal pattern.

4. A device according to any preceding Claim, characterised in that the microprocessor (1) is arranged to provide a first, real time clock operative to indicate normal time; a second clock indicating elapsed pregnancy time; a third clock indicating remaining pregnancy time; and a fourth clock to indicate the time taken for a predetermined number of operations of the switch, each operation corresponding to a fetal movement, and a counter associated with the fourth clock.

5. A device according to Claim 4, characterised in that an audible or visual signal is made when the time to start the first fetal movement monitoring period is reached by the fourth clock.

6. A device according to Claim 5, characterised in that an audible alarm signal is made if no input signals are received after three successive fetal monitoring periods.

7. A device according to any preceding Claim,
characterised in that the microprocessor is arranged to
store recorded information and display it on demand on the
display means (4).

8. A device according to any preceding Claim
characterised in that the device is in the form of a
wristwatch, pendant or bracelet.

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FIG.1.

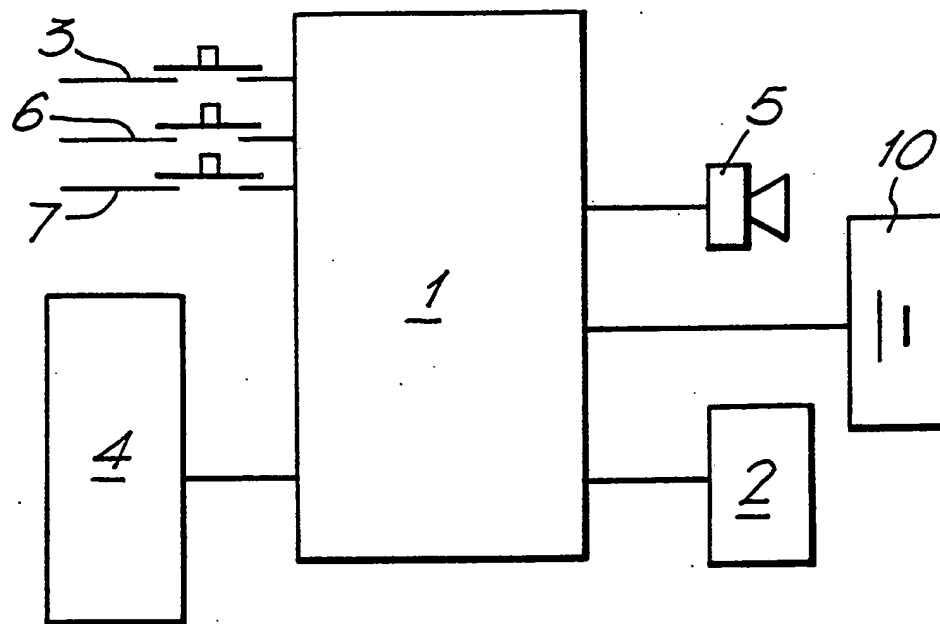
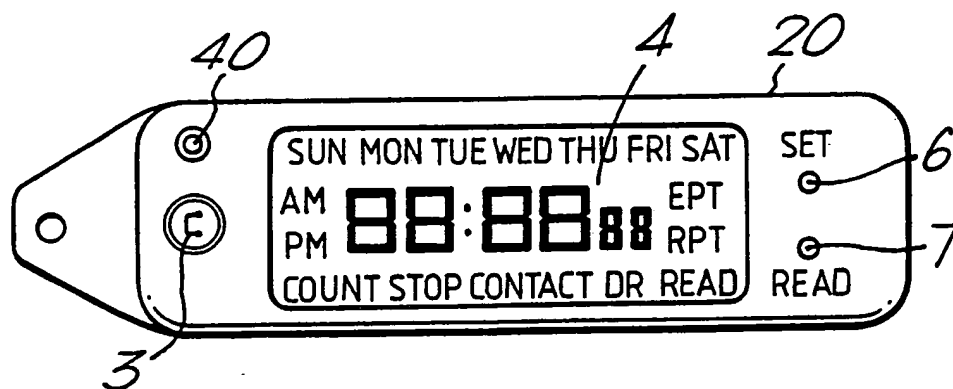


FIG.2.



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FIG.3a.

Modes and RegistersMode

- 0 Wait for kick counting to start, display time
- 1 Count kicks
- 2 Count complete, store result
- 3 Abnormal kick count detected
- 4 Read kick counts for past 7 days (including today)
- 5 Read EPT - Elapsed Pregnancy Time
- 6 Read RPT - Remaining Pregnancy Time
- 7 Set Registers for Time, Gotime, EPT

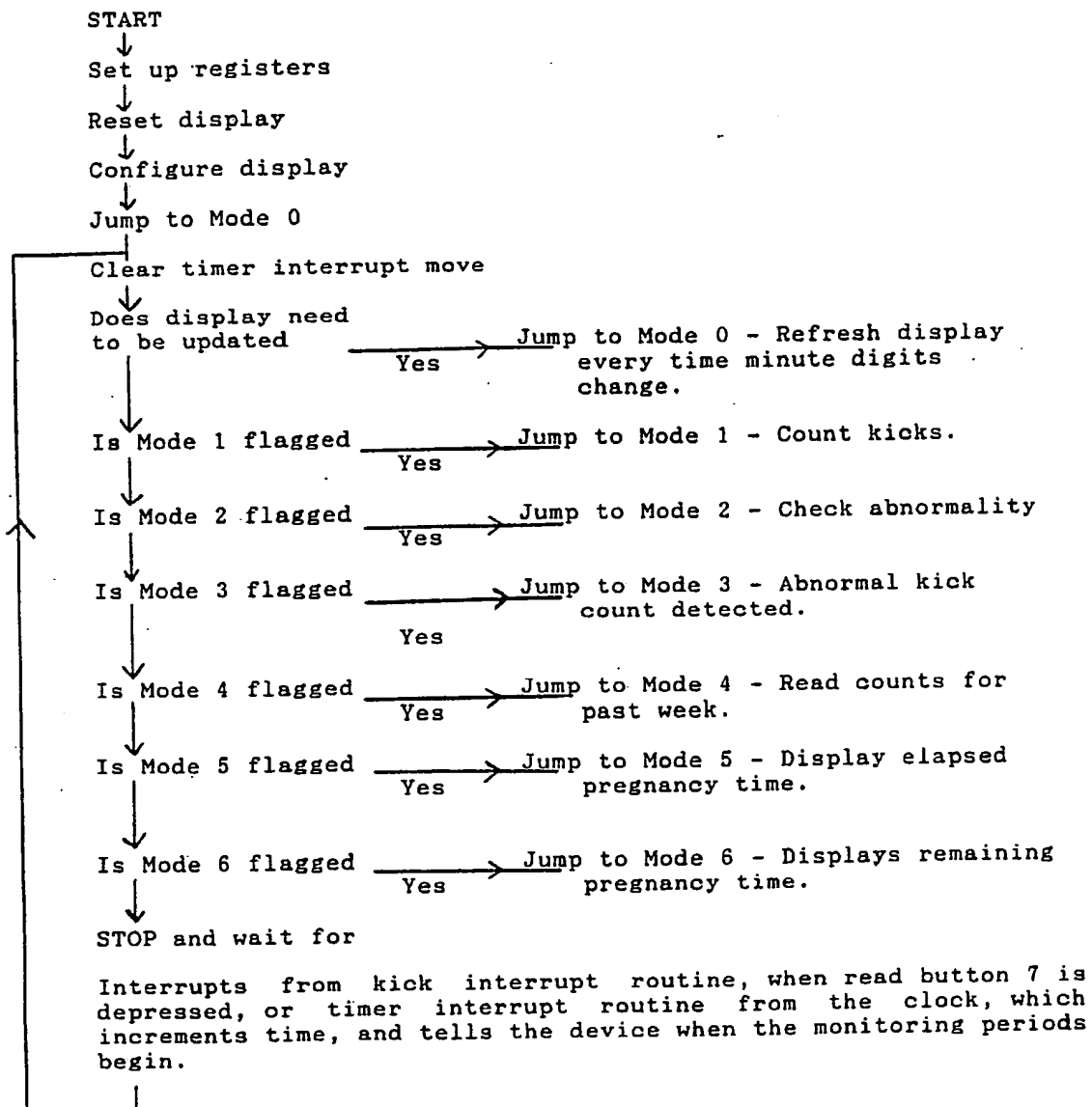
Register

- TIME S Stores current time (secs) (0-60)
- TIME M Stores current time (mins) (0-60)
- TIME H Stores current time (hours) (1-12)
- TIME D Stores current time (day) (1-7)
- NKICKS Stores current Number of Kicks counted
- STOREM, X Seven registers i.e. STOREM, 1 - STOREM, 7
- STOREH, X holding values in TIMEM, TIMEH and NKICKS
- STOREK, X at the end of the counting period. The value of X specifies the day.
- GOTIME Time chosen by the wearer for start of daily count
- FLAG 8 bits used for flagging various events i.e. Display update
- MODE 8 bits used to show which mode is active
- EPTW Elapsed pregnancy time Weeks
- EPTD Elapsed pregnancy time Days

SUBSTITUTE SHEET

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FIG.3b.

Outline Program

SUBSTITUTE SHEET

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 87/00804

| I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ⁴ According to International Patent Classification (IPC) or to both National Classification and IPC IPC ⁴ : A 61 B 5/10 | | | | | | | | | | | | | | | | | | | | |
|---|--|-------------------------------------|---|--|-------------------------------------|----------------|--|---------------------------------|------------------------|---|-------|---|----|---|---|---|---------|---|--|-------|
| II. FIELDS SEARCHED <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black; margin: 5px 0;">Minimum Documentation Searched ⁷</div> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%; border-bottom: 1px solid black; padding: 5px;">Classification System</td> <td style="border-bottom: 1px solid black; padding: 5px;">Classification Symbols</td> </tr> <tr> <td style="padding: 5px;">IPC⁴</td> <td style="padding: 5px;">A 61 B; G 04 G</td> </tr> </table> <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black; margin: 5px 0;">Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸</div> | | | Classification System | Classification Symbols | IPC ⁴ | A 61 B; G 04 G | | | | | | | | | | | | | | |
| Classification System | Classification Symbols | | | | | | | | | | | | | | | | | | | |
| IPC ⁴ | A 61 B; G 04 G | | | | | | | | | | | | | | | | | | | |
| III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹ <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%; padding: 5px;">Category ⁹</th> <th style="width: 70%; padding: 5px;">Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²</th> <th style="width: 20%; padding: 5px;">Relevant to Claim No. ¹³</th> </tr> </thead> <tbody> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">Y</td> <td style="padding: 5px;">GB, A, 2154768 (DATAFACE LTD) 11 September 1985 see abstract; figures 1,2; page 2, line 26 - page 3, line 24; page 3, line 46 - page 4, line 17; page 4, lines 78-108 --</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1,4,7</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">Y</td> <td style="padding: 5px;">Patent Abstracts of Japan, volume 2, no. 106, 31 August 1978, page 5562 E 78, & JP, A, 5370862 (SUWA SEIKOSHA K.K.) 23 June 1978 --</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1,4,7</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">A</td> <td style="padding: 5px;">--</td> <td style="text-align: center; vertical-align: top; padding: 5px;">8</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">A</td> <td style="padding: 5px;">WO, A, 83/02015 (FORBATH) 9 June 1983 see figures 1,2a; page 8, line 18 - page 10, line 10; page 27, line 2 - page 30, line 31 --</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1,2,4,7</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">A</td> <td style="padding: 5px;">US, A, 4367527 (DESJACQUES) 4 January 1983 see figures 1,5,9; column 1, lines 45-48; column 2, lines 54-64; column 3, line 36 - column 4, line 55; column 5, line 63 - column 9, line 47 --</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1,4,7</td> </tr> </tbody> </table> | | | Category ⁹ | Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹² | Relevant to Claim No. ¹³ | Y | GB, A, 2154768 (DATAFACE LTD) 11 September 1985 see abstract; figures 1,2; page 2, line 26 - page 3, line 24; page 3, line 46 - page 4, line 17; page 4, lines 78-108 -- | 1,4,7 | Y | Patent Abstracts of Japan, volume 2, no. 106, 31 August 1978, page 5562 E 78, & JP, A, 5370862 (SUWA SEIKOSHA K.K.) 23 June 1978 -- | 1,4,7 | A | -- | 8 | A | WO, A, 83/02015 (FORBATH) 9 June 1983 see figures 1,2a; page 8, line 18 - page 10, line 10; page 27, line 2 - page 30, line 31 -- | 1,2,4,7 | A | US, A, 4367527 (DESJACQUES) 4 January 1983 see figures 1,5,9; column 1, lines 45-48; column 2, lines 54-64; column 3, line 36 - column 4, line 55; column 5, line 63 - column 9, line 47 -- | 1,4,7 |
| Category ⁹ | Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹² | Relevant to Claim No. ¹³ | | | | | | | | | | | | | | | | | | |
| Y | GB, A, 2154768 (DATAFACE LTD) 11 September 1985 see abstract; figures 1,2; page 2, line 26 - page 3, line 24; page 3, line 46 - page 4, line 17; page 4, lines 78-108 -- | 1,4,7 | | | | | | | | | | | | | | | | | | |
| Y | Patent Abstracts of Japan, volume 2, no. 106, 31 August 1978, page 5562 E 78, & JP, A, 5370862 (SUWA SEIKOSHA K.K.) 23 June 1978 -- | 1,4,7 | | | | | | | | | | | | | | | | | | |
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| A | US, A, 4367527 (DESJACQUES) 4 January 1983 see figures 1,5,9; column 1, lines 45-48; column 2, lines 54-64; column 3, line 36 - column 4, line 55; column 5, line 63 - column 9, line 47 -- | 1,4,7 | | | | | | | | | | | | | | | | | | |
| <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>¹⁰ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div> | | | | | | | | | | | | | | | | | | | | |
| IV. CERTIFICATION <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; border-bottom: 1px solid black; padding: 5px;">Date of the Actual Completion of the International Search</td> <td style="width: 50%; border-bottom: 1px solid black; padding: 5px;">Date of Mailing of this International Search Report</td> </tr> <tr> <td style="padding: 5px;">11th July 1988</td> <td style="padding: 5px;">25 JUL. 1988</td> </tr> <tr> <td style="border-bottom: 1px solid black; padding: 5px;">International Searching Authority</td> <td style="border-bottom: 1px solid black; padding: 5px;">Signature of Authorized Officer</td> </tr> <tr> <td style="padding: 5px;">EUROPEAN PATENT OFFICE</td> <td style="padding: 5px;">M. VAN MOL </td> </tr> </table> | | | Date of the Actual Completion of the International Search | Date of Mailing of this International Search Report | 11th July 1988 | 25 JUL. 1988 | International Searching Authority | Signature of Authorized Officer | EUROPEAN PATENT OFFICE | M. VAN MOL | | | | | | | | | | |
| Date of the Actual Completion of the International Search | Date of Mailing of this International Search Report | | | | | | | | | | | | | | | | | | | |
| 11th July 1988 | 25 JUL. 1988 | | | | | | | | | | | | | | | | | | | |
| International Searching Authority | Signature of Authorized Officer | | | | | | | | | | | | | | | | | | | |
| EUROPEAN PATENT OFFICE | M. VAN MOL | | | | | | | | | | | | | | | | | | | |

| III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET) | | |
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ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

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This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 14/07/88. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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